MANDAVA ASSOCIATES, LLC

CONSULTANTS IN SCIENCE, TECHNOLOGY AND REGULATORY AFFAIRS
1050 CONNECTICUT AVENUE, N.W., SUITE 1000, WASHINGTON, DC 20036
Telephone: (202)-223-1424/1747 · Fax: (202)-223-0141 · E-MAIL: Mandava@compuserve.com

September 29, 2011

Mr. Jose Gayoso
Chemical Review Manager
Risk Management and Implementation Branch II
Pesticide Re-evaluation Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

SUBJECT: Request for Suspension
Product Name: Streptomycin Sulfate
Reconsideration of the Data Requirements under two DCIs

Dear Mr. Gayoso:

Thank you for your e-mail (see below) as a follow-up to our conference call meeting with you, Ms. Manibusan and others on September 19, 2011 (Monday).

As I explained to all of you at that meeting, the Agency seems to be unrealistic in imposing costly data requirements (about $2 million) on the registrants, at a time when the streptomycin sales are declining (and when growers are using streptomycin in alternate years - alternating with oxytetracycline). Repar maintains, as was mentioned at the meeting, the following points which we ask the Agency to consider/reconsider.

1) Re. Low volume - minor use exemption (LVE) - The Agency stated that it cannot grant the LVE to Repar Corporation ("Repar") when other registrants agreed to develop the data. [It is the assumption of Repar that the Agency already recognizes that streptomycin is a low volume minor use chemical and meets the definition of minor use chemical under FQPA.]

2) If the Agency recognizes that streptomycin is a low volume minor use chemical, why does not the EPA consider reducing the data burden rather than stating that other companies are willing to develop the data? [Repar believes that FIFRA allows the Agency to make the determination that the data is burdensome to registrants, and there is no economic benefit. This is because of low use and low exposure which would result in negligible risk to humans and the environment.]

3) The Agency is concerned about resistance problems from streptomycin. Repar has shown in previous submissions that streptomycin use (through formulations) does not contribute to resistance.

4) Non-target organisms (e.g. birds, mammals, insects, aquatic animals and plants) could be exposed to streptomycin in the environment. Recently, Canada's PMRA has determined that streptomycin is unlikely to affect non-target organisms [through revised label directions]. We ask the Agency to review this decision before imposing a costly burden of data requirements.

5) If there are other environmental concerns (e.g., effect on non-target organisms), Repar is not convinced that streptomycin for pesticidal use is the root cause for those concerns. [Repar is aware that FDA approves streptomycin for animal use which would result in significant exposure to the environment.] Other factors that would contribute streptomycin exposure to the environment are likely to include native *Streptomyces* and agricultural applications of animal waste, among others.

6) Repar does not know whether EPA has discussed with FDA, the exposure of streptomycin to the environment as a result of animal use.

7) Since the EPA has the authority under FIFRA to collect the environmental fate and ecological effects data, it is Repar's opinion that the registrants will have to bear the costs for all these studies, although pesticide exposure does not seem to be the root cause for resistance and other ecological effects.

Repar, a small company, is not willing to assume the severe financial burden to develop the data imposed by the Agency and requests the Agency to not impose the data requirement. [Even if Repar joins the Task Force, it will have to commit about $500,000, a substantial sum, as its portion for the development of the required data.]

Repar has repeatedly requested the EPA to reconsider the data requirements under the two Data Call-In Notices (DCIs). Repar is appealing the Agency's decision on the above grounds which include:

1. Cost benefit analysis;
2. Low volume minor use considerations; and,
3. The fact that pesticide exposure does not contribute to resistance and environmental problems.

If problems arise from non-pesticidal uses of streptomycin, the Agency should not penalize the registrants using the authority under FIFRA [using Section 3(c)(2)(b)], by simply believing that all the problems arise from pesticidal uses, not streptomycin use for animals and also others, if any. Repar does not believe that the Agency has unequivocally determined that all the problems are due to streptomycin use for agriculture.

Repar respectfully asks the Agency to consider or reconsider the above points for not imposing this data burden. As it is, if the data requirements stand, then Repar, stating its position, will have no choice but to request suspension of its registration at this time.

Repar fully understands that suspending the product registrations will cause severe hardship to itself since Repar cannot market the registered products. After taking into the consideration of all the economic aspects, however, Repar is requesting the Agency to suspend the product registrations for streptomycin.

Sincerely,

N. Bhushan Mandava

N. Bhushan Mandava, Ph.D.
Agent for Repar Corporation

Cc: Mary Manibusan

RE: Streptomycin registration
Bhushan Mandava
to:
Jose Gayoso
09/16/2011 01:36 PM
Cc:
Mary Manibusan, Cathryn Britton
Hide Details
From: "Bhushan Mandava" <mandava@compuserve.com>

To: Jose Gayoso/DC/USEPA/US@EPA

Cc: Mary Manibusan/DC/USEPA/US@EPA, Cathryn Britton/DC/USEPA/US@EPA

History: This message has been replied to.

Dear Mr. Gayoso:

Since our last telephone conversation in July 2011, we have been collecting additional information on the data available in public domain on streptomycin. We have not assembled it for submission to EPA.

We have been attempting to convince the Agency to waive the burdensome data requirements for streptomycin. We noted that the Agency stated that Repar's registration would not be eligible for waiver for a low volume/minor use because other technical registrants have committed to conduct the studies. We have provided the information that Repar Corporation is a small company and the sales do not support the development of the required data. [We have also given you the sales volumes for streptomycin published by USDA and others, and we stated that the declining use volumes do not justify the costs for the development of the required data.]

Re. Environmental Fate and non-Target Organisms Data: We have provided the open literature data to satisfy the required environmental fate and non-target organisms studies. The Agency accepted only one study (850.4400) and denied the waivers for other studies.

We are providing you the additional information as noted below:

1) Low Volume/Minor Uses: We are really surprised to note that the Agency denied our request for a low volume/minor use exemption (LVE). We did not get a convincing reason why such an exemption cannot be granted (not to one registrant but) to all the registrants of streptomycin. Under the law, the Agency can grant such an exemption provided that the registrants showed the reasonable grounds. [Regardless of others making such a LVE request, the Agency can make such determination without requests from the registrants for Public good.] The underlying basis for such an exemption is low exposure and negligible risk because of low volume use. Inherently, streptomycin has a low toxicity (based on the toxicity data); it was not proved to be a carcinogen or a mutagen, and it did not show other toxic effects. It is a naturally occurring substance. The Agency can regulate streptomycin by restricting its use if it is a man-made, but cannot control it when it is produced by nature.

2) Source(s) for Streptomycin Resistance: We understand the resistance problems but we are not clear where the resistance is coming from (about the source for resistance). We have provided the published information that clearly demonstrates that the streptomycin formulations do not contribute to resistance problems.[Additionally a 1999 Wisconsin Study shows that the DNA, including antibiotic resistance genes, is either absent or present at low, undetectable levels in plant-grade antibiotic formulations. It is unlikely that growers are enriching the environment with antibiotic resistance genes when they spray streptomycin to control fire blight.]
If streptomycin formulations do not contribute to resistance, what is the source for resistance? If the resistance comes from other sources such as animal wastes, we are not sure that EPA has the authority to require such data from the streptomycin registrants under FIFRA. Data aren't just being required to study resistance.

3) Radio-Labeled C-14 Streptomycin for Environmental Fate Studies: We support the Nufarm/Makhteshim request for waiver. It would be difficult to make radio (C-14) labeled material (or other radio-labeled materials using different isotopes) to conduct environmental fate studies. The approach suggested by EPA does not seem to be practical. If we conduct these studies with cold material (unlabeled streptomycin), one has to use a large amount of the material, and the identity of the degradation products or metabolites would be very difficult by chromatographic analysis coupled with UV/Vis spectrometric detection systems. Since there are no chromophores in the streptomycin molecule, it would be difficult to identify the breakdown products. The results that we would get from such studies would not be significantly different from what have been reported previously. This is because we will be employing the same old technology for isolation and characterization of the breakdown products (what we call it a BUCKET CHEMISTRY, not micro analytical work). Other sophisticated expensive detection methods such as LC/MS and MS/MS are considered to be the research tools and not the practical methods. We have already ~~resp~~ denied this waiver, and the registrants are

4) Cost-Benefit Approach: Economically, it does not make sense to develop the data required by EPA, because it does not seem to be a cost-benefit approach for streptomycin. There are other registrants willing to satisfy the requirements

I will be available for a conference call meeting with you and your branch chief on Monday afternoon (after 1 PM) or on Tuesday. Please let me know what would be the convenient time for both of you, so that I will make myself available.

Cost benefit analyses on mitigation, not DCI.

Also, this only applies to foreign (what's the excuse for export)

Best Regards,

N. Bhushan Mandava
Mandava Associates, LLC
1050 Connecticut Avenue, N.W.
Suite 1000
Washington, D.C. 20036
Tel: (202) 223 - 1424
Fax: (202) 223 -0141

-----Original Message-----
From: Gayoso.Jose@epamail.epa.gov [mailto:Gayoso.Jose@epamail.epa.gov]
Sent: Thursday, September 15, 2011 11:58 AM
To: Bhushan Mandava
Cc: Manibusan.Mary@epamail.epa.gov; Britton.Cathryn@epamail.epa.gov
Subject: Streptomycin registration

Dr. Mandava,
The last time we spoke, in July of this year, I asked that you provide us with an update on how Repar intends to comply with the data requirements for streptomycin. I mentioned that your registration would not be eligible for a low volume/minor use since other streptomycin technical registrants have committed to conduct studies.

I would like to schedule a phone call with you, my branch chief, and myself. Please let me know when you would be available next week.

Thank you,

9/14/11 (phone call w/ Mandava)
- Repar can't afford to cost share.
- Request EPA to suspend registration.
- Will email by sept.

☆ follow up email ☆

~~EOS~~ Suspension - when would registration be deleted

MANDAVA ASSOCIATES, LLC

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September 29, 2011

Mr. Jose Gayoso
Chemical Review Manager
Risk Management and Implementation Branch II
Pesticide Re-evaluation Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

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Sincerely,

N. Bhushan Mandava

N. Bhushan Mandava, Ph.D.
Agent for Repar Corporation

Cc: Mary Manibusan

MANDAVA ASSOCIATES, LLC

CONSULTANTS IN SCIENCE, TECHNOLOGY AND REGULATORY AFFAIRS
1050 CONNECTICUT AVENUE, N.W., SUITE 1000, WASHINGTON, DC 20036
Telephone: (202)-223-1424/1747 Fax: (202)-223-0141 E-MAIL: Mandava@compuserve.com

October 12, 2010

Jose Gayoso
Chemical Review Manager
Risk Management and Implementation Branch II
Pesticide Re-Evaluation Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

SUBJECT: Streptomycin (Case # 0169)
Chemical Name: Streptomycin Sulfate
Chemical Number: 006310
Generic Data Call-In ID# RR-006310-28469
Registration Review Issued June 22, 2010
EPA Reg. No.: 69361-8

Company: Repar Corporation

Dear Mr. Gayoso:

In response to the Agency's Generic Data Call-In (DCI) for Streptomycin Sulfate (EPA Reg. No.: 69361-8); ID #RR-006310-28469, Repar Corporation ("**Repar**") is submitting the following information:

1) Completed and signed Data Call-In Response Form
2) Completed and signed Requirements Status and Registrants Response Form
3) Letter addressed to you informing the Agency how Repar intends to satisfy all the data required under the subject GDCI Notice.

Please be advised that we are not submitting the Cost Share Form (EPA Form 8570-32) because Repar is seeking waivers (Response Codes 8 and 9) for the required data (as shown in the attached letter to you. Repar is also not submitting the Certification with Respect to Data Compensation Requirements (EPA Form 8570-31) because Repar is not relying on other' generic data for streptomycin under the subject GDCI Notice. To the best of our knowledge, no other company owns the data or submitted to EPA the generic data required under the subject GDCI Notice.

Since the **REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM** does not provide adequate space for indicating the options (Options 8 and 9), we request you to consider the attached letter for complete details.

We have submitted additional information in several attachments in support of Repar's response to Generic Data Call-In Notice for Streptomycin.

If there are further questions, please contact us at (202) 223-1424.

Sincerely,

N. Bhushan Mandava

N. Bhushan Mandava, Ph.D.
Agent for Repar Corporation

Enclosure

United States Environmental Protection Agency Washington, D.C. 20460

OMB Approval 2070-0174

OMB Approval 2070-0107
OMB Approval 2070-0057

DATA CALL-IN RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
REPAR CORP 1050 CONN. AVE., N.W., SUITE 1000 WASHINGTON, DC 20036	0169 Streptomycin Chemical # and Name 006310 Streptomycin sulfate	22-Jun-2010 GENERIC ID # RR-006310-28469

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
69361-8	NO	NO	YES	N.A.	N.A.

8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative N. Bhushan Mandava Registration Agent

9. Date 10-12-10

10. Name of Company Repar Corporation

11. Phone Number (202) 223-1424

United States Environmental Protection Agency Washington, D.C. 20460

OMB Approval 2070-0174

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
REPAR CORP 1050 CONN. AVE., N.W., SUITE 1000 WASHINGTON, DC 20036	0169 Streptomycin Chemical # and Name 006310 Streptomycin sulfate	22-Jun-2010 GENERIC ID # RR-006310-28469

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
	Environmental Fate Data Requirements (Conventional Chemical)								
835.4200	Anaerobic soil metabolism					Q, A, B, C	TGAI or PAIRA	24	8 and 9
835.4300	Aerobic aquatic metabolism					Q, A, B, C	TGAI or PAIRA	24	8 and 9
835.4400	Anaerobic aquatic metabolism					Q, A, B, C	TGAI or PAIRA	24	8 and 9
	Nontarget Plant Protection Data Requirements (Conventional Chemical)								
850.4100	Terrestrial plant toxicity, Tier 1 (seeding emergence)					Q, A, B, C	TEP	12	8 and 9
850.4150	Terrestrial plant toxicity, Tier 1 (vegetative vigor)					Q, A, B, C	TEP	12	8 and 9
850.4400	Aquatic plant toxicity test using Lemna spp. Tiers I and II (2)					Q, A, B, C	TEP or TGAI	12	8 and 9
850.5400	Algal toxicity, Tiers 1 and II (1)					Q, A, B, C	TEP or TGAI	12	9
	Product Chemistry Data Requirements (Conventional Chemical)								
830.7370	Dissociation constants in water (4)					Q, A, B, C	TGAI or PAI	8	9
	Terrestrial and Aquatic Nontarget Organisms Data Requirements (Conventional Chemical)								

10. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law

Signature and Title of Company's Authorized Representative N. Bhushan Mandava Registration Agent

11. Date 10-12-10

12. Name of Company Repar Corporation

13. Phone Number (202) 223-1424

United States Environmental Protection Agency Washington, D.C. 20460

OMB Approval 2070-0174

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address

REPAR CORP
1050 CONN. AVE., N.W., SUITE 1000
WASHINGTON, DC 20036

2. Case # and Name

0169 Streptomycin
Chemical # and Name 006310
Streptomycin sulfate

3. Date and Type of DCI and Number

22-Jun-2010
GENERIC
ID # RR-006310-28469

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
850.1300	Daphnid chronic toxicity test (5 ,6)					Q, A, B, C	TGAI	12	9
850.1400	Fish early-life stage toxicity test (7 ,8)					Q, A, B, C	TGAI	12	8 and 9
850.2300	Avian reproduction test (3 ,9)					Q, A, B, C	TGAI	24	8 and 9

Initial to indicate certification as to information on this page (full text of certification is on page one). NBM

Date 10-12-10

MANDAVA ASSOCIATES, LLC

CONSULTANTS IN SCIENCE, TECHNOLOGY AND REGULATORY AFFAIRS
1050 Connecticut Avenue, N.W. Suite 1000, WASHINGTON, DC 20036-4549
TELEPHONE: (202)-223-1424/1747 · TELEFAX: (202)-223-0141 · E-MAIL:mandava@compuserve.com

October 13, 2010

HAND DELIVERED

Project ID: Repar Corporation – Submission of Generic Data Call In Response for Streptomycin products

To: Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Today, I received an unopened package containing the documents and administrative material for Streptomycin products for Repar Corporation and addressed to:

Mr. Jose Gayoso
Special Review and Reregistration Division (7508P)
Office of Pesticide Programs
OPPTS
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

Signature: P. E Moore

Printed Name: P E MOORE

Date: 10/13/10

***NOTE TO COURIER:**

AFTER DELIVERING THE PACKAGE, PLEASE HAVE THE RECIPIENT SIGN THIS DELIVERY RECEIPT AND PLACE IN ENCLOSED STAMPED, SELF ADDRESSED ENVELOPE AND DROP IN THE NEAREST MAIL BOX. THANK YOU.

MANDAVA ASSOCIATES, LLC

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1050 Connecticut Avenue, N.W. Suite 1000, WASHINGTON, DC 20036-4549
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